

REMARKS

Reconsideration is respectfully requested in view of the above amendments and the following remarks.

Status of Claims Following May 7, 2003 Office Action

In the May 7, 2003 Office action, the Examiner indicated on Form PTO-326 that claims 1, 3, and 72 and 73 were objected to and claims 2 and 4-85 are rejected. From the substantive action it appears that the Examiner objected to claims 1-85 and rejected claims 2, 4-71, and 74-83. Therefore it would appear that claims 2, 4-71, and 74-83 stand rejected and claims 1, 3, 72-73 and 84-85 stand objected to. Applicants request clarification of the status of the claims following the May 7, 2003 Office action.

Summary of Amendments Submitted in This Response

In this response, Applicants have amended claims 1-3 and 5-83; and have cancelled claim 4. After entry of these amendments, claims 1-3, and 5-85 will be pending.

Applicant's cancellation or amendment of these claims does not indicate that Applicants acquiesce to the Examiner's rejections. Applicants reserve the right to pursue in future applications identical or similar claims to those cancelled or amended.

Applicants have amended claims 1-3 to clarify the claimed invention. Applicants have amended claims 5-71, and 74-83 to change "methods of treating or preventing" to "methods of treating" and to change "effective to treat or prevent" to "effective to prevent." Applicants have also amended claims 5-83 to conform these claims to the amendments made in claims 1-2.

RESPONSE TO SPECIFIC OBJECTIONS AND REJECTIONS.

Response to Election/Restriction Objections

Applicants appreciate the Examiner's acknowledgement of the election of species with traverse of (1R,2R)/(1S,2S)-2-(4-Morpholinyl)-1-(2-naphthalenethoxy)cyclopentane.

In the May 7, 2003 Office action, the Examiner identifies a subset of the compounds of claim 1 for examination with the elected embodiment and states that the remaining subject matter of claims 1-85 is withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

Applicants note that the subject application entered the US national phase as a section 371 filing from PCT application CA00/00117. As set forth in MPEP 1893.03(d), "Examiner's are reminded that unity of invention (not restriction) practice is applicable in ... national phase applications submitted under 35 U.S.C. § 371." Thus, the claims in the current application must be reviewed under the unity of invention standards and not under restriction requirement standards. 37 CFR 1.142(b) applies to restriction requirements, and the Examiner's application of 37 CFR 1.142(b) is not therefore appropriate.

Treatment of Unity of Invention for Markush Group Claims

In the May 7, 2003 Office action, the examiner sets forth a subset of claim 1 that he identifies for examination and requests amendment to limit claim 1 to the identified subject matter. Claim 1 is a Markush type claim. The correct standard for unity of invention for Markush type claims is set forth in MPEP 1850, subsection D, which states that

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

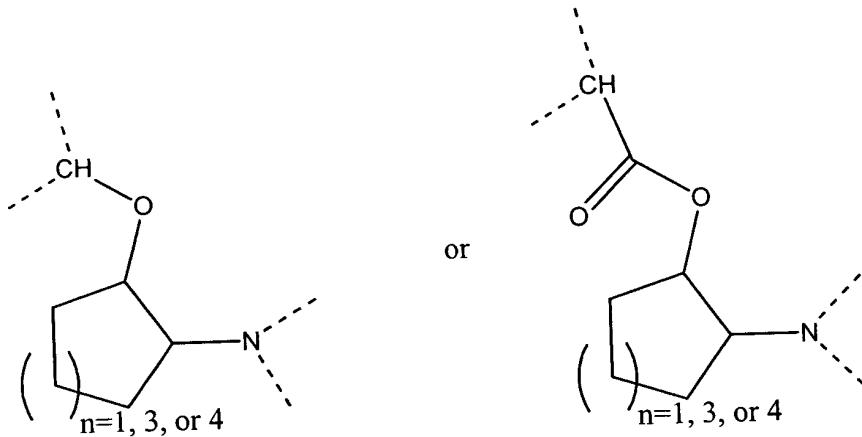
(C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Regarding the meaning of a “significant structural element” as used in section (B)(1) above, MPEP 1850, subsection D 1 states that this refers to two cases: (1) where the compounds share a common chemical structure which occupies a large portion of their structures, or (2) in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. Appendix AI, Annex B, Part 2 III of the MPEP sets forth examples of Markush claims for which unity of invention is present and is not present.

Under the standard set forth above, a Markush claim possesses unity of invention unless the compounds within the Markush group either (1) do not share a common utility, or (2) do not share a significant common structural element or belong to a recognized class of chemical compounds.

As described in the specification, the compounds of the Markush group set forth in claim 1 may be used in pharmaceutical compositions for the treatment of conditions including but not limited to arrhythmia. The compounds within the Markush group therefore share a common utility.

The compounds of the Markush group are all 2-amino cycloalkyl esters or ethers with a carbon bonded to the ether or ester group and with the cycloalkyl group being cyclopentyl, cycloheptyl or cyclooctyl. That is, all compounds in the group share the common structural element of



This molecular fragment is a significant structural element in the molecules set forth in the Markush group.

Because the compounds in the claim 1 Markush group possess a common utility and share a significant common structural element, unity of invention is present.

Applicants also note that the PCT examiner, applying the above described standards for determination of unity of invention, did not reject claim 1 for lack of unity of invention.

In light of the foregoing remarks, the Examiner is respectfully requested to withdraw the objection to claims 1-85 and withdraw the request that Applicants limit claim 1 to the subject matter identified by the Examiner.

Response to Claim Rejections Under 35 U.S.C. § 101

The Examiner has rejected claims 4-7 under 35 U.S.C. § 101 as including an improper definition of a process because the claims set forth a use without setting forth any steps involved in the process.

Applicants have cancelled claim 4, and have amended claims 5-7 to include the steps of the claimed methods.

The claims as amended conform with 35 U.S.C. § 101, and Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 101 rejections of claims 4-7.

Response to Claim Rejections Under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 5, 8-71, and 74-83 under 35 U.S.C. § 112, first paragraph, contending that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically the Examiner rejects claims 5, 8-71, and 74-83 as lacking support in the specification for *preventing* the claimed disorders.

Applicants have amended claims 5, 8-71, and 74-83 to change “methods of treating or preventing” to “methods of treating” and to change “effective to treat or prevent” to “effective to treat.” These amendments do not indicate that Applicants acquiesce to the Examiner’s rejections, and Applicants reserve the right to pursue in future applications identical or similar claims to those amended.

The claims as amended conform with 35 U.S.C. § 112, first paragraph, and Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejections of claims 5, 8-71, and 74-83.

Response to Claim Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 2 and 4-7 under 35 U.S.C. § 112, second paragraph, contending that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejects claims 4-7 as being indefinite because they merely recite a use without any active, positive steps. Applicants have cancelled claim 4, and have amended claims 5-7 to include the steps of the methods.

The Examiner rejects claim 2 as unclear as to whether applicants intend to claim a compound or mixture comprising compounds. Applicants have amended claim 2 to claim a composition comprising a component selected from various compounds, mixtures of compounds, and pharmaceutically acceptable salts and solvates thereof.

The Examiner rejects claims 5-7 as being drawn to two statutory classes of invention: a compound and a composition. Applicants have amended claims 1 and 2 to be drawn to compositions comprising compounds and mixtures of compounds and have amended claims 5-7 to be drawn to using compositions according to claims 1-3.

The claims as amended conform with 35 U.S.C. § 112, second paragraph, and Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, second paragraph rejections of claims 2 and 4-7.

CONCLUSION

Applicants have responded to each matter raised in the May 7, 2003 Office action and believe the application to be in condition for allowance.

In the event that there are any questions, comments, or suggestions concerning this amendment or the application in general, or if an interview is considered desirable, the Examiner is requested to telephone the undersigned representative so that prosecution may be expedited.

In the unlikely event that the Patent Office determines that an extension and/or other relief is required as a result of this statement, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due to our **Deposit account no. 03-1952** referenced Docket No. 554792000500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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